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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,865	12/16/2003	Guo-Liang Yu	PF343PID1	5457
22195	7590	07/12/2006	EXAMINER	
HUMAN GENOME SCIENCES INC. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			BUNNER, BRIDGET E	
			ART UNIT	PAPER NUMBER
			1647	
DATE MAILED: 07/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/735,865

Applicant(s)

YU ET AL

Examiner

Bridget E. Bunner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16, 21, and 23, drawn to an isolated nucleic acid molecule of SEQ ID NO: 1, classified in class 536, subclass 23.1.
  - II. Claims 17-18, 20, and 22, drawn to an isolated neutrokin- $\alpha$  polypeptide, classified in class 530, subclass 350.
  - III. Claim 19, drawn to an isolated antibody that binds neutrokin- $\alpha$ , classified in class 530, subclass 387.1.
  - IV. Claim 23, drawn to an isolated nucleic acid molecule of SEQ ID NO: 7, classified in class 536, subclass 23.1.
  - V. Claim 23, drawn to an isolated nucleic acid molecule of SEQ ID NO: 8, classified in class 536, subclass 23.1.
  - VI. Claim 23, drawn to an isolated nucleic acid molecule of SEQ ID NO: 9, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

- a. Inventions I-III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Groups I-III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. For example, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such as a probe in nucleic acid hybridization assays. The protein of

Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

Furthermore, searching the inventions of Groups I-III together would impose a serious search burden. In the instant case, the search for the DNA, protein, and protein are not coextensive.

- b. Inventions I and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, each of SEQ ID NOs: 1, 7, 8, and 9 (Groups I and IV-VI, respectively), is a unique nucleotide sequence, requiring a unique search of the prior art. Each nucleic acid sequence is a different length and is composed of different nucleic acids. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.
- c. Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, each of SEQ ID NOs: 7, 8, and 9 (Groups IV-VI, respectively), is a unique nucleotide sequence, requiring a unique search of the prior art. Each nucleic acid sequence is a different length and is composed of different nucleic acids. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

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- d. Inventions II/III and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Groups II/III and IV-VI are unrelated products, wherein each is not required, one for another. For example, the isolated protein of Invention II is not used or generated from the nucleic acid products of Inventions IV-VI. The isolated antibody of Invention III is also not used or generated by the nucleic acid products of Inventions IV-VI. Furthermore, searching the inventions of Groups I/II and IV-VI together would impose a serious search burden. In the instant case, the search for the DNA, protein, and protein are not coextensive.

2. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
Art Unit 1647  
10 July 2006

*Bridget E. Bunner*

**BRIDGET BUNNER  
PATENT EXAMINER**